UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,911	11/28/2001	Richard B. Mazess	017620-9335	4126

23510 7590 07/09/2003

MICHAEL BEST & FRIEDRICH, LLP
ONE SOUTH PINCKNEY STREET
P O BOX 1806
MADISON, WI 53701

EXAMINER
CRIARES, THEODORE J

ART UNIT	PAPER NUMBER
1617	10

DATE MAILED: 07/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,911	MAZESS, RICHARD B.	
	Examiner	Art Unit	
	Theodore J. Criares	1617	

-- The MAILING DATE of this communication app ars on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-55* is/are pending in the application.

4a) Of the above claim(s) *35-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,10-34 and 42-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6 & 7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

CLAIMS 1, 3-8 AND 9-55 ARE PRESENTED FOR EXAMINATION

DETAILED ACTION

Applicant's election with traverse of group I, claims 1, 3-8, 10-34 and 42-55 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the claims are directed to **embodiments of the same invention**. This is not found persuasive because an undue burden is placed on the examiner since both the application claims method of use and compositions which places an undue burden on the examiner in view of the required search of the pharmceutical literature. The pharmaceutical art has established that the method of treating a medical disorder and the compositions for said treatment are separate and distinct inventions as previously set forth in the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claims 35-41 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 3-8, 9-35 and 42-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for " A method of inhibiting hyperproligeration of malignant or neoplastic cells". The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification neither provides sufficient information that all the malignant cells associated with cancers are treatable nor that the of the active agents administered once per week to about once per 12 weeks for all the cancers set forth in claim 3 will be effective.

3. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a method of inhibiting hyperproliferation of malignant or neoplastic cells in a subject with an effective amounts of a an astronomical number of variousf Vitamin D compounds. The nature of the invention is extremely complex in that it encompasses the actual treatment of many various cancers as can be seen from claim 3.

Breath of the Claims: The complex of nature of the subject matter of this invention is greatly exacerbated by breath of the claims. The claims encompass inhabition of a complex cell proliferation disorder in humans which has potentially many different causes (i.e. many different mutations or combination of mutations). Each of which may or may not be addressed by the administration of the claimed compounds.

Guidance of the Specification: The guidance given by the specification as to how one would administered the claimed compounds to a subject in order to actually prevent all the cancer's claimed in claim 3 is minimal. All of the guidance provided by the specification is directed towards treatment of specific cancers in a specific concentration of the claimed compounds. The claims are also confusing since there is guidance given at page 14 that an episodic dose (claim 1) is a single dose or divided into 2-4 subdoses and claims similar to claim 14 require the dose to be given once per seek to once every 12 weeks.

Working Examples: All of the working examples provided by the specification are directed toward the treatment of specific cancers and specific amounts in a specific time period.

State of the Art: While the state of the art is relatively high with regard to treatment of specific cancers, the state of the art with regard to treating cancer or neoplasms broadly is undeveloped. In particular, there is no known anticancer agent which is effective against all cancers. The Carter et al. reference clearly teaches that for the forty known anticancer agents, none art effective against all cancers. (see pages 362-365 of carter et al reference.)

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual treatment of all cancers as set forth, in for example claim 3, in a human subject with the claimed compounds makes practicing the claimed invention unpredictable.

The amount of Exp rimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test the combination in the model system to determine whether or not the combination is effective for inhibiting hyperproliferation of malignant or neoplastic cells in all cases. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regard treatment of cancer with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding treatment of cancer with any compound, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to inhibit hyperproliferation of malignant or neoplastic cells in a subject by administration of one or combination of the claimed compounds.

Therefore, a method inhibiting hyperproliferation of malignant or neoplastic cells administering the claimed Vitamin D compounds is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims 1,3-6, and 10 are rejected under 35 U.S.C. 102(a) as being anticipated by Knutoson et al. (5,798,345).The claims in the cited reference claim the method of inhibiting the hyperproliferation of malignant cells with a Vitamin D compound with a hydrocarbon at C-24. The episodic dose, as stated above, can be a single dose. The statement in applicant's claims that there is a reduced risk of hypercalcemia and the cells express a Vitamin D receptor would be inherent in the claimed activity.

DOUBLE PATENTING

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 3-8, 9-35 and 42-55 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-44 of prior U.S. Patent No. 6,503,893. This is a double patenting rejection.

Claim 7 of the cited patent, which depends from claim 6, is drawn to the episodic administration of a Vitamin D compound in a method of inhibiting the hyperproliferative activity of malignant or neoplastic cells. Claims 20-28 of the application read on the administration of the active agent once a week. Therefore, the double patenting rejection of these claims is deemed proper. The claims are also confusing since there is guidance given at page 14 that an episodic dose (claim 1) is a single dose or divided into 2-4 subdoses and claims similar to claim 14 require the dose to be given once per seek to once every 12 weeks.

None of the claims are allowed.

Applicant is advised to review his portfolio of patents since the claims of the present application may be anticipated or be subject to further rejections.on the basis of a Double Patenting.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is 308-4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Theodore J. Criares can be reached on 305-1877. The fax phone numbers

for the organization where this application or proceeding is assigned are 703-746-6897 for regular communications and N/A for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Theodore J. Criares
Primary Examiner
Art Unit 1617

tjc
July 8, 2003